Report Documentation Page

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1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
30 JUL 2010	**Final Report**	**19-12-2009 to 01-06-2010**

4. TITLE AND SUBTITLE
Gleevec in the Treatment of Inflammatory Arthritis

5a. CONTRACT NUMBER
5b. GRANT NUMBER
5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Matthew Carroll

5d. PROJECT NUMBER
5e. TASK NUMBER
5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
81st Medical Group,301 Fisher St,Keesler AFB,MS,39534

8. PERFORMING ORGANIZATION REPORT NUMBER
FKE20100008E

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
81st Medical Group, 301 Fisher St, Keesler AFB, MS, 39534

10. SPONSOR/MONITOR'S ACRONYM(S)
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11. SPONSOR/MONITOR'S REPORT NUMBER(S)
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Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Tyrosine Kinase inhibitors are an area of rapidly evolving medications in Rheumatoid Arthritis. There is currently no information beyond case reports and thus a retrospective review of a large database of records of patients could yield additional insight about the true efficacy of Gleevec in treating inflammatory arthritis. While 13 records were identified in the search of M2 requested by this protocol, only 2 records had enough information in AHLTA for a meaningful review. Of these 2, only 1 satisfied the search criteria but only partial records were available.

15. SUBJECT TERMS
Gleevec; Inflammatory Arthritis; Tyrosine Kinase Inhibitor, M2

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**1**	**2**	

81st Medical Group
Keesler AFB, Mississippi

Exempt (Human) Research Protocol

This is a Progress Report _____ / Final Report _XX_

1. **Protocol Number: FKE20100008E**

2. **Title: Gleevec ® in the Treatment of Inflammatory Arthritis**

3. **Principal Investigator (PI):** Matthew B. Carroll, Lt Col, USAF, MC, FACP, FACR, 81 MDOS/SGOMJ, Phone 228-376-3829, Beeper 057, Email matthew.carroll@keesler.af.mil

4. **Purpose:**
Tyrosine Kinase inhibitors are an area of rapidly evolving medications in Rheumatoid Arthritis. Inhibitors of JAK2 and Syk have already been evaluated in proof of concept / Phase II trials. Currently tyrosine kinase inhibitors are FDA approved for use in the treatment of hematologic / oncologic conditions. Specifically the medications Gleevec ® (imatinib) and others in this class (Sprycel ® (dasatinib), Tasigna ® (nilotinib), and Sutent ® (sunitinib)) are being used to treat Chronic Myelogenous Leukemia, Gastrointestinal Stromal Tumors (GIST), Myelodysplastic Syndrome, Systemic Mastocytosis, and other hematologic malignancies. Case reports suggest that patient's with inflammatory arthritis such as Rheumatoid Arthritis who then start a medication like Gleevec ® due to the development of a hematologic malignancy actual have improvement in multiple parameters of their arthritis. There is currently no information beyond case reports and thus a retrospective review of a large database of records of patients could yield additional insight about the true efficacy of Gleevec ® in treating inflammatory arthritis.

5. **Status of the Study.** Mark the status of the study (a-e).

   a. _____ Active with ongoing data collection. Request approval to remain open.

   b. _____ Active with data collection complete. Request approval to remain open.

   c. _____ Study was never initiated and request termination of the study.

   d. _X_ Completed, research implemented and results available. Request approval to close.

   e. _____ Inactive, protocol never initiated, but want to keep in open. Request approval to remain open.

6. **Summary of Progress:** This report covers the following period of time: 16 Dec 09 – 1 Jun 10.

   a. Since last progress report or initiation of study:
   Search of M2 yielded was performed in mid-March 2010 with a review of information in AHLTA performed in early April 2010. The search yielded 13 records but on chart review (using AHLTA) only two patients had enough information for review. Of these 2, only 1 satisfied the search criteria (a patient with Rheumatoid Arthritis started on Gleevec for Gastrointestinal Stromal Tumor) but only partial records were available.

   b. For the entire study: I have completed 100% of the study.

   c. If this is a FINAL REPORT:

      1. Were the protocol objectives met and how will the outcome benefit the DoD/USAF?
      The protocol objectives were met. While the search of M2 did not yield publishable data, it did provide a first step forward to searching M2 for future studies by understanding the limitations in transitioning from M2 to AHLTA for records reviews.

2. Protocol Outcomes Summary:
While 13 records were identified in the search requested by this protocol, only 2 records had enough information in AHLTA for a meaningful review. Of these 2, only 1 satisfied the search criteria but only partial records were available; the other was not a case of inflammatory arthritis but of hypereosinophilic syndrome.

7. Protocol Changes: N/A

a. _____ No changes are anticipated and the project will continue as previously approved by the IRB.

b. _____ Changes are anticipated as described below: *(Description.....)*

8. Protocol Personnel Changes:

Has there been any Principal or Associate Investigator (PI/AI) changes since approval of protocol or the last continuation review? ___ Yes _XX__ No. If yes, complete the following sections (Additions/Deletions). For PI/AI changes, indicate whether or not the IRB approved this change.

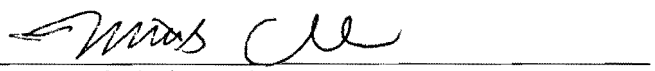
a. Additions: *(Include Name, Protocol function - PI/AI IRB approval - Yes/No)*
b. Deletions: *(Include Name, Protocol function - PI/AI, Effective date of deletion)*

9. Status of Approved Funding: No funding in support of this study was requested.

10. Publications/Presentations/Awards: None.

11. Certification of Principal Investigator

My signature certifies that the above titled research has been conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. I understand that a Progress Report is required in order to maintain continuation approval and any changes in the study/methodology must be approved by the IRB prior to implementation. If the study has never been initiated and I am requesting termination (Item 5.c. above), my signature certifies this request. If the study is completed (Items 5.d. & 6.c. above) and I am requesting closure, my signature certifies that the information provided on this form represents an accurate final report.



Signature of Principal Investigator

7/30/10
Date

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